Complete Summary

GUIDELINE TITLE

Preventive foot care in people with diabetes.

BIBLIOGRAPHIC SOURCE(S)

Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. Diabetes Care 2003 Jan;26 Suppl 1:S78-9. [2 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Foot ulcers
- Diabetes mellitus

GUIDELINE CATEGORY

Evaluation
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Emergency Medicine
Endocrinology
Family Practice
Internal Medicine
Physical Medicine and Rehabilitation
Podiatry

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physician Assistants
Physicians
Podiatrists

GUIDELINE OBJECTIVE(S)

- To update the evidence for various preventive and therapeutic modalities to decrease diabetic foot ulcers and lower-extremity amputations
- To provide clinical practice recommendations for diabetic people with no foot ulcers and to outline the best means to identify and manage risk factors before a foot ulcer occurs or an amputation becomes imminent

TARGET POPULATION

Diabetic adults with unulcerated feet

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment

1. Identification of risk factors for development of ulcers or amputations
2. Annual comprehensive foot examination, including:
    - Neurological assessment (protective sensation, quantitative somatosensory threshold test)
    - Vascular assessment (claudication history and pedal pulses)
    - Assessment of biomechanical status
    - Assessment of skin integrity

Prevention and Management of High Risk Conditions

1. Prevention of high risk conditions for foot ulcers (i.e., neuropathy, vascular disease), including maintenance of glycemic levels to as near normal as possible and encouragement of smoking cessation
2. Management of high-risk conditions, such as:
    - Footwear selection and management in people with neuropathy or evidence of increased plantar pressure
    - Callus debridement in people with increased plantar pressure
    - Consideration of exercise therapy and surgical options after further vascular assessment in people with symptoms of claudication
    - Treatment of minor skin conditions, such as dryness and tinea pedis
3. Patient education
4. Provider education

MAJOR OUTCOMES CONSIDERED

- Morbidity, disability, and emotional and physical costs associated with foot ulcers and amputations for people with diabetes
- Risk and rate of foot ulcers or amputations

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

In the Technical Review, the type of evidence for studies on prognosis, risk factor identification, and interventions was scored using a modification of the U.S. Preventive Services Task Force Criteria:

I-A: Randomized controlled trial, crossover trials
I-B: Controlled trial, nonrandomized
II-A: Cohort, case-control
II-B: Time series, pre-post studies, repeated panel
II-C: Cross-sectional population-based data
III: Descriptive studies
Case series, case reports
IV: Expert opinion and consensus opinion
X: Meets all of the screening and diagnosis criteria*
Y: Meets part of the screening and diagnosis criteria*

*Screening and diagnostic test criteria: (1) gold standard, preferably a patient outcome that matters rather than a disease; (2) definitions of the test and the outcomes are clear and easily reproduced; (3) test characteristics: sensitivity, specificity, reproducibility provided; (4) subjects: population-based preferred over selected populations; and (5) tests that provided results early in the disease course are preferred to ones that can only be used late in the course, especially if effective early intervention is possible.

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The paper was peer-reviewed, modified, and approved by the American Diabetes Association's Professional Practice Committee and Executive Committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Please note: This guideline has been updated as of January 2004. The National Guideline Clearinghouse is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Risk Identification

Risk identification is fundamental for effective preventive management of the foot in people with diabetes. The risk of ulcers or amputations is increased in people who have had diabetes $\geq$10 years, are male, have poor glucose control, or have cardiovascular, retinal, or renal complications. The following foot-related risk conditions are associated with an increased risk of amputation:

- Peripheral neuropathy with loss of protective sensation
- Altered biomechanics (in the presence of neuropathy)
    - Evidence of increased pressure (erythema, hemorrhage under a callus)
    - Bony deformity
- Peripheral vascular disease (decreased or absent pedal pulses)
- A history of ulcers or amputation
- Severe nail pathology

Foot Exam

All individuals with diabetes should receive an annual foot examination to identify high-risk foot conditions. This examination should include assessment of protective sensation, foot structure and biomechanics, vascular status, and skin integrity. People with one or more high-risk foot conditions should be evaluated more frequently for the development of additional risk factors. People with neuropathy should have a visual inspection of their feet at every visit with a health care professional. Evaluation of neurological status in the low-risk foot should include a quantitative somatosensory threshold test, using the Semmes-Weinstein 5.07 (10-g) monofilament. Initial screening for peripheral vascular disease should include a history for claudication and an assessment of the pedal pulses. The skin should be assessed for integrity, especially between the toes and under the metatarsal heads. The presence of erythema, warmth, or callus formation may indicate areas of tissue damage with impending breakdown. Bony deformities, limitation in joint mobility, and problems with gait and balance should be assessed.

Prevention of High-Risk Conditions

Distal symmetric polyneuropathy is one of the most important predictors of ulcers and amputation. The development of neuropathy can be delayed significantly by maintaining glycemic levels to as near normal as possible. Smoking cessation should be encouraged to reduce the risk of vascular disease complications.

Management of High-Risk Conditions

People with neuropathy or evidence of increased plantar pressure may be adequately managed with well-fitted walking shoes or athletic shoes. Patients should be educated on the implications of sensory loss and the ways to substitute other sensory modalities (hand palpation, visual inspection) for surveillance of early problems. People with evidence of increased plantar pressure (e.g., erythema, warmth, callus, or measured pressure) should use footwear that cushions and redistributes the pressure. Callus can be debrided with a scalpel by a foot care specialist or other health professional with experience and training in foot care. People with bony deformities (e.g., hammertoes, prominent metatarsal heads, bunions) may need extra-wide shoes or depth shoes. People with extreme bony deformities (for example, Charcot foot) that cannot be accommodated with commercial therapeutic footwear, may need custom-molded shoes. People with symptoms of claudication should receive further vascular assessment. Exercise therapy and surgical options may be considered.

People with a history of ulcers should be evaluated for the underlying pathology that led to the ulceration and be managed accordingly. Minor skin conditions such

as dryness and tinea pedis should be treated to prevent the development of more serious conditions.

Patient Education

Patients with diabetes and high-risk foot conditions should be educated regarding their risk factors and appropriate management. A nonjudgmental assessment of a person's current knowledge and care practices should be obtained first. Patients at risk should understand the implications of the loss of protective sensation, the importance of foot monitoring on a daily basis, the proper care of the foot, including nail and skin care, and the selection of appropriate footwear. The patient's understanding of these issues and their physical ability to conduct proper foot surveillance and care should be assessed. Patients with neuropathy should be advised to break in new shoes gradually to minimize the formation of blisters and ulcers. Patients with visual difficulties, physical constraints preventing movement, or cognitive problems that impair their ability to assess the condition of the foot and to institute appropriate responses will need other people, such as family members, to assist in their care. Patients at low risk may benefit from education on foot care and footwear.

Provider Education

All health care providers of people with diabetes should be able to conduct a simple screening exam of the neurological, vascular, dermatological, and musculoskeletal systems. Providers with interest in the foot may choose to obtain additional training and provide focused management of high-risk foot conditions. Additional expertise in patient education, footwear modifications, nail and callus care, and surgical management of the foot may be needed.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- The early recognition and management of independent risk factors for foot ulcers and amputations can prevent or delay the onset of morbidity, disability, and emotional and physical costs for people with diabetes.
- Diabetic foot care programs involving relatively simple and inexpensive interventions may decrease the amputation rate up to 85%.

POTENTIAL HARMS

None stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM. Preventive foot care in people with diabetes. Diabetes Care 2003 Jan;26 Suppl 1:S78-9. [2 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 (reviewed 2000 Jan; republished 2003 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association received an educational grant from LifeScan, Inc., a Johnson & Johnson Company, to support publication of the 2003 Diabetes Care Supplement.

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The initial draft of this paper was prepared by: Jennifer A. Mayfield, MD, MPH (chair); Gayle E. Reiber, PhD, MPH; Lee J. Sanders, DPM; Dennis Janisse, CPed; Leonard M. Pogach, MD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Orthopedic Foot and Ankle Society
American Podiatric Medical Association - Medical Specialty Society

GUIDELINE STATUS

Please note: This guideline has been updated as of January 2004. The National Guideline Clearinghouse is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the updated guideline: Available from the American Diabetes Association (ADA) Web site.

Print copies: Available from American Diabetes Association, 1701 North Beauregard Street, Alexandria, VA 22311.

AVAILABILITY OF COMPANION DOCUMENTS

The recommendations in this paper are based on the evidence reviewed in the following publication:

- Mayfield JA, Reiber GE, Sanders LJ, Janisse D, Pogach LM: Preventive foot care in people with diabetes (Technical Review). Diabetes Care 1998;21:2161-77.

Print copies: Available from the American Diabetes Association (ADA), 1701 North Beauregard Street, Alexandria, VA 22311.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on April 2, 2001. The information was verified by the guideline developer on August 24, 2001. The summary was updated by ECRI on January 29, 2002 and April 21, 2003.

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